REMARKS

THE CLAIM AMENDMENTS

Claims 69, 73, 92, and 93 are canceled with this amendment.

Claim 68 has been amended to delete the phrase "associated with inflammation" and to add subject matter from canceled claims 69, 73, and 93.

THE LEGAL FRAMEWORK FOR THE EXAMINER'S PRIMA FACIE CASE

The *prima facie* case is a procedural tool which, as used in patent examination, means not only that the evidence of the prior art would reasonably allow the conclusion the Examiner seeks, but also that the prior art compels such a conclusion if the applicant produces no evidence or argument to rebut it. *In re Spada,* 911 F.2d 705 (Fed. Cir. 1990). If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more, the applicant is entitled to a grant of the patent. *In re Oetiker,* 977 F.2d 1443 (Fed. Cir. 1992).

The following discussion outlines the Examiner's *prima facie* case and presents arguments in rebuttal of same.

ENABLEMENT REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claim 68-77, 84-87, 92, and 94-99 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabling. This rejection is moot for canceled claim 92.

Applicants have amended independent claim 68 so that it recites the subject matter identified by the Examiner as enabling at item 8 of the Office Action; this subject matter was previously recited in canceled claim 93. In light of the amendment to claim 68, applicants respectfully request reconsideration and withdrawal of this rejection.

Applicants' state that the amendment provided in response to the Examiner's rejection is presented solely to expedite the prosecution of this application and does not represent acquiescence with the substance of the Examiner's rejection.

THE WRITTEN DESCRIPTION REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 68-77, 84-87, 92, and 94-99 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This rejection is moot for canceled claim 92.

The Examiner identifies the following phrases as lacking support: "treating skin conditions, disorders, and diseases associated with inflammation" from claim 68 and "inhibiting cellular events associated with tumor initiation, promotion, and progression" from claim 92.

Applicants have amended claim 68 to remove the phrase identified by the Examiner and have canceled claim 92. In light of the amendment to claim 68 and the cancellation of claim 92, applicants respectfully request reconsideration and withdrawal of this rejection.

Applicants' state that the amendment provided in response to the Examiner's rejection is presented solely to expedite the prosecution of this application and does not represent acquiescence with the substance of the Examiner's rejection.

THE ANTICIPATION REJECTION UNDER 35 U.S.C. § 102(e)

Claims 68, 84-87, 92-95, 98, and 99 stand rejected under 35 U.S.C. § 102(e) as anticipated by Carson et al. This rejection is moot for canceled claims 92 and 93.

Claim 68 has been amended to incorporate the subject matter of canceled claims 69 and 73, both of which were not included in this rejection. With the incorporation of the subject matter of claims 69 and 73 into claim 68, it follows that the rejected claims are no longer within the purview of this rejection; accordingly, applicants respectfully request reconsideration and withdrawal of this rejection.

Applicants' state that the amendment provided in response to the Examiner's rejection is presented solely to expedite the prosecution of this application and does not represent acquiescence with the substance of the Examiner's rejection.

THE ANTICIPATION REJECTION UNDER 35 U.S.C. § 102(b)

Claims 68 and 92 stand rejected under 35 U.S.C. § 102(b) as anticipated by Hou. This rejection is moot for canceled claim 92.

Because claims 69 and 73 were not included in this rejection, it follows that with the incorporation of the subject matter of claims 69 and 73 into claim 68, claim 68 is no longer within the purview of this rejection; accordingly, applicants respectfully request reconsideration and withdrawal of this rejection.

Applicants' state that the amendment provided in response to the Examiner's rejection is presented solely to expedite the prosecution of this application and does not represent acquiescence with the substance of the Examiner's rejection.

THE OBVIOUSNESS REJECTION UNDER 35 U.S.C. § 103(a) OVER CARSON ET AL.

Claims 68-77, 84-87, and 92-99 stand rejected under 35 U.S.C. § 103(a) as obvious over Carson et al. This rejection is moot for canceled claim 92 and is traversed for the remaining claims.

Carson et al. teaches a topical cosmetic formulation containing resveratrol for application on the surface of the skin of a human subject. Carson et al. teaches that the topical formulation may be a lotion, a cream, or a gel (col. 6, ll. 50-51). Carson et al. does ***not*** teach or suggest that the topical formulation may be modified for oral or parenteral administration nor does Carson et al. suggest that the topical formulation may be modified for any type of administration other than for topical administration on the surface of the skin.

Despite the unequivocal teaching from Carson et al. that the topical formulation disclosed therein is contemplated for and intended only for administration on the surface of the skin of a human subject, the Examiner asserts that Carson et al. renders the claimed invention obvious. In support of this position, the Examiner argues that the microemulsion limitation in claim 68 is an "intended use" limitation that does not add any structural features to the claimed formulation. The Examiner attempts to justify this specious argument by emphasizing that the alleged "intended use" is the oral and parenteral "administration" of the microemulsion.

In response to the Examiner's assertion, applicants note first and foremost that the Examiner is wrong. To assert that a dosage form and a mode of administration of a pharmaceutical formulation is an intended use and not a structural limitation turns the fine art of pharmacy on its head.

The faulty reasoning in the Examiner's arguments is evident from the following except, which is found at page 3 of the Office Action:

> [A] recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention over the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *See, In re Casey*, 152 USPQ 235 (CCPA) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

As a preliminary matter, applicants note that the present invention does not include a "process of making"; the claims are strictly pharmaceutical formulation claims. Notwithstanding the foregoing, applicants note that the recitation in claim 68 that the pharmaceutical formulation is a microemulsion for oral and parenteral administration is not an intended use limitation; it *is a **structural limitation** that sets forth the metes and bounds of the pharmaceutical formulation.*

The structural characteristic of the claimed pharmaceutical formulation has clearly escaped the Examiner as it appears that the Examiner finds that the term "for oral or parenteral administration" to be an intended use. Applicants thus, must take this opportunity to correct the Examiner and explain that the intended use of the claimed pharmaceutical formulation is ***not*** its oral or parenteral administration; rather, it is the treatment of the recited diseases, i.e., the treatment of psoriasis, contact dermatitis, atopic dermatitis, actinic keratosis, keratinization disorders, epidermolysis bullosa diseases, exfoliative dermatitis, seborrheic dermatitis, erythemas, discoid lupus erythematosus, and dermatomyositis. The oral and parenteral administration of the microemulsion containing the resveratrol describes the dosage form of the pharmaceutical formulation, in other words, it describes a pharmaceutical formulation that is prepared by way of a microemulsion of resveratrol that is taken either orally or parenterally. The recitation of the terms "orally" and "parenterally" limit the metes and bounds by which the microemulsion may be used. These are critical limitations in that they distinguish the pharmaceutical formulation of the claimed invention from those microemulsions that are applied topically.

Solely for the sake of argument, applicants note that the Examiner's argument would have some merit were it applied against the true intended use limitations in claim 68, i.e., the treatment of psoriasis, contact dermatitis, atopic dermatitis, actinic keratosis, keratinization disorders, epidermolysis bullosa diseases, exfoliative dermatitis, seborrheic dermatitis, erythemas, discoid lupus erythematosus, and dermatomyositis. Applicants removed this "intended use" limitation from the claims in the previous amendment on the awareness that the recitation did not add any patentable subject matter to claim 68, but have reintroduced the recitation back into claim 68 in response to the Examiner's enablement rejection. Upon removing the intended use limitation, applicants replaced it with ***a structural limitation***, i.e., the recitation that the pharmaceutical formulation is a microemulsion for oral or parenteral administration.

Turning next to the Examiner's cited case law, applicants note that these cases do not support the Examiner's position that the "oral and parenteral administration" of the pharmaceutical formulation is an "intended use" limitation.

In *Casey*, the invention at issue was a tape dispenser supported by a rotary brush with open-ended bristles. The primary prior art reference was directed to a perforating machine wherein sheets of paper are supported by a rotary brush with open-ended bristles and the secondary reference was directed to a tape dispensing machine with a dispensing drum rotatably mounted on supporting means The Board of Appeals for the Patent Office ("the Board") held that the tape dispenser was obvious over the cited references because the adhesive tape and the sheets of paper are held onto the same structures, i.e., a rotary brush that supports a band of material. In other words, the manner of use of the machine, i.e., the

"intended use" with either an adhesive or a paper, did not serve to render the tape dispensing machine patentable over the perforating machine. *Casey*, 152 USPQ at 238.

Comparing *Casey* to the claimed invention, it is once again obvious that the intended use of the claimed invention is the treatment of the diseases. Just as the machine in *Casey* can be used to either dispense tape or to perforate paper, so the pharmaceutical formulation of claimed invention may be used to treat any one of the recited diseases. By contrast, just as the device in *Casey* can be altered within the scope of the claims ***structurally*** so that it may be used to either dispense tape or to perforate paper, so too can the pharmaceutical formulation be administered in a microemulsion for oral or parenteral administration depending on which disease it is being used to treat.

In *Otto*, the invention at issue was a device for curling hair and a method of making the device; the gist of the invention was an elastically resilient core member made of foam material to which dry hair is wound and then wetted. Seven references were asserted against the claimed invention, some of which were directed to hair curlers and others directed to a core member of absorbent material provided with a dentrifice, which is activated by contact with a liquid. The Board refused to consider the procedure by which the hair is curled when comparing the invention against the prior art on the grounds that the curling of the hair was a method outside the claimed device. *Otto*, 136 USPQ at 459.

Comparing *Otto* to the claimed invention, applicants note that *Otto* would only have application were applicants asserting that the method of treating any of the diseases is the distinguishing characteristic of the invention, but as already noted more than once, applicants are not asserting as much. Further, applicants are not asserting any method of oral administration or of parenteral administration with the claimed invention, they are merely asserting that the claimed pharmaceutical formulation is for oral or parenteral administration, which is essentially a recitation of the type of dosage form contemplated under the invention. In light of the foregoing, applicants submit that *Otto* does not support the Examiner's position.

Because the claimed invention is not rendered obvious over Carson et al. for the reasons set forth above, applicants respectfully request reconsideration and withdrawal of this rejection.

OBVIOUSNESS REJECTION UNDER 35 U.S.C. § 103(a) OVER ASHIDA

Claims 68-77, 84-87, and 92-99 stand rejected under 35 U.S.C. § 103(a) as obvious over Ashida. This rejection is moot for canceled claim 92 and is traversed for the remaining claims.

The Examiner's rejection of the claimed invention over Ashida is based upon the same grounds as the Examiner's rejection of the claimed invention over Carson et al.; accordingly, the same arguments set forth for Carson et al. also apply for Ashida. In light of the foregoing, because the claimed invention

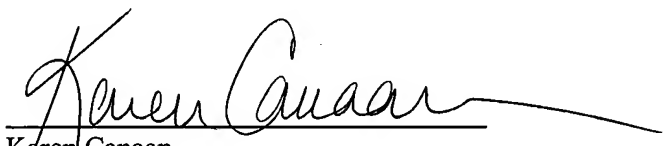
is not rendered obvious over Ashida for the reasons set forth in the discussion of Carson et al., applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

Each of the Examiner's rejections have been fully addressed and overcome. Because the Examiner has failed to establish a *prima facie* case against the claimed invention, applicants are entitled to a patent grant on the claimed invention; accordingly, applicants respectfully request withdrawal of all claim rejections and passage of this application to issue.

If the Examiner has any questions regarding this amendment that may be addressed by way of a telephone call or e-mail correspondence, he is encouraged to contact the undersigned at 650-330-4913 or at canaan@reedpatent.com.

Respectfully submitted,



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